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Response to Letters to the Editor from Irit Sinai "Standard Days Method Effectiveness: opinion disguised as scientific review" and Kelsey Wright, Karen Hardee, and John Townsend "The pitfalls of using selective data to represent the effectiveness, relevance and utility of the Standard Days Method of contraception"

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We find ourselves bemused by the tone of these letters and the unfounded speculation about partiality and “opinion disguised as scientific review”. For the record, our position on SDM is simply the same as our position on all contraceptive methods: that users should know how effective it is and should be informed about the full range of other methods, including highly effective ones.

Hardee et al suggest we “repeatedly misquote” evidence – though offer just one supposed instance from a single point in our paper (p.493): “The stakes are high: an ineffective family planning method may increase recourse to abortion. For instance, one 15-country study showed periodic abstinence failure contributed to one sixth of all foetal losses most of which were likely to be illegal induced abortions.[1]” We should have made clearer that this was all foetal losses **following contraceptive failure** – but the study still supports our basic point: that ineffective methods may increase recourse to abortion.

Hardee et al also say we “missed the point” that some women will want to use SDM, but this is not relevant to the question of the method’s effectiveness or how its effectiveness is presented to clients.

One serious criticism the writers make is that our study is based on a selective and inaccurate reading of the evidence. Both letters suggest a number of other studies they claim contradict our findings. We address each supposed omission below, explaining why each was not included. But, to be clear, this study looks at the evidence for the effectiveness of SDM (typical use effectiveness comparable to the population-level typical use estimates available for other methods and perfect use effectiveness) – and not, for instance, how users feel about the method, or the profile of those users.

We would highlight seven errors in the text of the letters:

1. Hardee et al. state “several studies show similar rates with typical use” but do not provide any evidence for this claim. Instead, they provide two irrelevant citations: Blair et al. [2] report on a qualitative study; Kalaca et al. [3] provide some information about pregnancies in their very small sample but do not report effectiveness, which the study was not designed to measure.

2. They say we miss two independent studies “on SDM integration” from Ethiopia, by Bekele et al [4] and Nigeria by Ujuju et al [5]. But these do not contain information on effectiveness, which is the reason why we did not include them.

3. Sinai says that we “ignored at least eight relevant articles” that oppose our views. Not one of the citations she provides opposes our findings, and six do not even contain information about effectiveness: four are studies already mentioned above[2-5]; two more by Lundgren et al do not measure effectiveness, one measures uptake of SDM in three sites [6], and one knowledge and attitudes [7]. One article [8] provides figures from intervention studies, not typical use (see also point 7 below). One final article [9] co-authored by Sinai, does at least contain information that could plausibly inform us about typical-use

effectiveness, but only inaccurately and not at a population level. As an author, Sinai will be aware that the study design (retrospective interviews with clinic users and clinical records review in two provinces in Peru) precludes population measurement of pregnancies and hence of effectiveness. Indeed, the authors of the original, longer report [10] of the same study explicitly warn "The study design would not allow calculation of accurate pregnancy rates" (p.4)

4. Sinai also suggests we should have included the qualitative study by Ujuju et al. [5] Yet this paper simply reports that some participants believed SDM was effective. The study does include reports that could inform broader work on SDM: the authors say that users seemed to practise withdrawal during the 'fertile' days, rather than using more reliable methods; that among polygamous users, the man simply moved between wives to avoid fertile periods; and that one woman in the study found SDM harder to use than the injectables she had switched away from, because it required "a lot of self control on his side" (p489).

5. Hardee et al. question the statement that SDM is marketed as rivalling pills and condoms. We provide links in the paper to promotional materials that compare SDM to pills and condoms, though not to more effective methods. We also supply an illustrative example here (see figure).

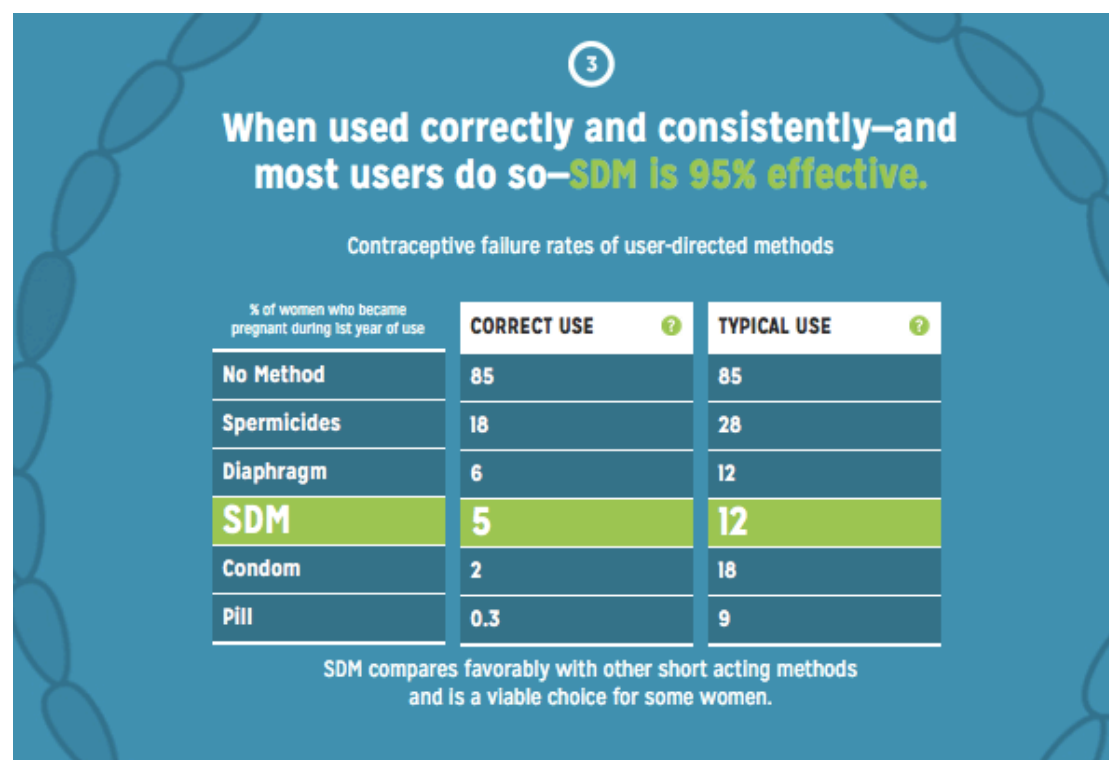


Figure: Example of SDM marketing materials. The text emphasises that SDM is 95% effective for "most users". Also that SDM "compares favourably with other short acting methods", which on the chart includes pills and condoms, but not injectables. Long-acting and permanent methods are also absent.

(Screenshot from standarddaysmethod.org on 27 May 2016)

6. Hardee et al. state that "consistent evidence, including reviews completed by WHO [they provide no citations], show that SDM offers significant improvement

over periodic abstinence or non-use". But they confuse abstinence and non-abstinence SDM. It is clear from the efficacy study[11] that the SDM tested is a form of calendar-based periodic abstinence.

7. Sinai argues there is no need for further studies of typical-use effectiveness as SDM implementation studies imply a typical use SDM failure rate of 14.1. However, this figure is based on data from clients who agreed to do follow-up interviews as part of implementation studies designed to measure feasibility and acceptability of SDM, not effectiveness. The authors themselves highlight weaknesses of the data such as loss to follow up, heterogeneity of the programmes, and self-reporting.[8] They add "follow-up interviews may have improved client knowledge and motivation to use the method. In addition, some participating organizations and providers may have been more enthusiastic about the SDM than would have been the case outside of a research context." p.150 [8] In addition, the methodology for combining the varied data sources is not specified and so we could not assess the quality of the synthesis.

Neither letter appears to take issue with the most important problem we raise: that the method tested and cited in promotional materials is *different* from the method now promoted worldwide: the first requires abstinence, the second does not.

Hardee et al.'s comment that the efficacy study was performed properly does not address the question of how the findings have been used: to promote a different version of SDM. We find it plausible that long periods of abstinence – more than half the cycle for most SDM users who also abstain during menses – will reduce pregnancies.

We are also puzzled by Hardee et al.'s suggestion that a method that relies on counting days – and indeed using proprietary CycleBeads® to help count these days – is not calendar-based.

Sinai seems to acknowledge a gap in the evidence in saying that it would be "helpful" to know the effectiveness of non-abstinence SDM – but stops short of calling for its promoters to stop citing figures from the Arevalo et al. efficacy study [11]. Incidentally, given the importance placed on the efficacy study by SDM proponents, we do think it would be useful to release the raw data.

Surely SDM users need to know that the method they are actually using may not be as effective as claimed. Users of back-up methods in particular must be told that the 95 per cent figure so prominent in promotional materials relies on abstinence. We also wonder if frequent users of back-up methods such as condoms are better viewed as SDM users – or simply as periodic users of condoms.

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